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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,863	08/14/2001	Megan K. Levings	DX01135	8706

7590 07/15/2002

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	1

DATE MAILED: 07/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/929,863	LEVINGS ET AL.
	Examiner Janet L Andres	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-9 and 11-18 is/are rejected.  
 7) Claim(s) 10 is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### *Specification*

1. The disclosure is objected to because of the following informalities: There is a missing page number in the reference on line 8 of p. 14. Page 3 contains references to unpublished U.S. patent applications. 08/643810 has issued as U.S. patent 6277635 and the specification should be updated accordingly. 07/846208 is abandoned. The Examiner notes that abandoned applications less than 20 years old can be incorporated by reference to the same extent as copending applications; both types are open to the public upon the referencing application issuing as a patent. See MPEP § 103: The incorporation by reference of a pending application in a U.S. patent application publication, a U.S. patent, or a published international application designating the United States constitutes a special circumstance under 35 U.S.C. 122 warranting that a copy of the application-as-filed be provided upon written request.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9 and 11-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working

examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

These claims are drawn to methods using IFN- $\alpha$  to induce differentiation of T cell precursors. However, Lin et al. (J. Exp. Med. 1998, vol. 187, pp. 79-87) teaches that treatment of T cell precursors with IFN- $\alpha$  blocks differentiation. Thus, one of skill in the art would not have predicted that using IFN- $\alpha$  would be successful, because Lin et al. teaches that it is not. Applicant teaches only that IFN- $\alpha$  induces differentiation of cord blood T cells, and teaches that it was unsuccessful in inducing the differentiation of peripheral blood T cells (pp. 7-9). Applicant further teaches on p. 9 that cord blood cells produce IL-10. Applicant further teaches on p. 10, line 23, that both factors are necessary for differentiation. Thus, one of skill in the art would not predict, based on the teachings of Lin et al. and those of the instant specification, that IFN- $\alpha$  would be sufficient to induce differentiation. Similarly, neither the instant specification nor the prior art provide guidance to indicate that addition of an “antigen” or proliferation using IL-15 would result in the claimed effect. There are no teachings in the instant specification to indicate what the effects of an “antigen” or “alloantigen” would be on differentiation, and none to indicate that addition of a proliferative agent would result in the production of Tr1 cells. The further limitations to the claims are means of characterizing the differentiated population and would have no effect on inducing such differentiation. Thus, without further guidance to allow the prediction of a successful outcome, it would require undue experimentation for the skilled artisan to practice the invention as claimed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite in the recitation of "said cells". It is not clear which cells are referred to. In addition, if the method is for increasing the number of Tr1 cells by proliferation, the contacted cells must be Tr1 cells.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Avi et al., Journal of Immunology, 1998, vol. 161, pp. 3408-3415.

The claims are drawn to methods using interleukin 15 to stimulate proliferation of Tr1 cells. Avi et al. teaches treatment of T lymphocytes purified from peripheral blood with interleukin 15. This treatment would inherently have resulted in proliferation of Tr1 cells that were present, thus anticipating the instant claims.

*Allowable Subject Matter*

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIMS 1-9 AND 11-18 ARE REJECTED. CLAIM 10 IS OBJECTED TO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[yvonne.eyler@uspto.gov\]](mailto:yvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
June 28, 2002

*Wonne EYLER*  
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